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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/526,760

03/04/2005

Peter Buehlmayer

NOV-10-US

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EXAMINER

DAVIS, BRIAN J

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

03/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/526,760 | Applicant(s) BUEHLMAYER ET AL. | |
| | Examiner Brian J. Davis | Art Unit 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

103 Rejections Maintained

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1, 2 and 8-10, in so far as they read on the species RN=177258-45-6 of WO 9606068 (CAPLUS abstract) under 35 U.S.C. 103(a) and outlined in the previous Office Action, is maintained for reasons of record. Applicant's amendment and arguments have been carefully considered, but are not persuasive.

As stated in the previous Office Action, adjacent homologs are considered to be obvious absent unexpected results. "Presumption of unpatentability arises against [a] claim directed to [a] composition of matter the adjacent homologue of which is old in [the] art; burden is on applicant to rebut presumption by showing that [the] claimed compound possess unobvious or unexpected beneficial properties not actually possessed by [the] prior art homologue; it is immaterial that [the] prior art homologue may not be recognized or known to be useful for [the] same purpose or to possess [the] same properties as [the] claimed compound...". This is so because: "[C]haracteristics normally possessed by members of homologous series are principally the same, and vary but gradually from member to member; chemists knowing properties of one member [of the] series would in general know what to expect of adjacent members." *In re Henze*, 85 USPQ 261, 263 (CCPA 1950). Members of a homologous series must possess unexpected properties not possessed by the homologous compounds disclosed in the prior art. *In re Hass*, 141 F.2d 127, 60 USPQ 548 (CCPA 1980).

Applicant principally argues that the narrowing of claim 1 by the inclusion of a single stereochemical center (see diagram of formula I) renders the claim set unobvious over the cited compound. However, the expectation with regard to enantiomers is that activities as they pertain to living systems are expected to be different. *In re Adamson*,

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275 F.2d 952, 125 USPQ 233 (CCPA 1960). The fundamentals of optical activity and stereoisomerism are well known to persons of ordinary skill in the art. One of ordinary skill would have known how to resolve the racemic mixture and would have been motivated to do so with the reasonable expectation that the two resulting enantiomers would have substantially different pharmacological activity. This is an expected result and it is well established that expected beneficial results are evidence of obviousness, just as unexpected beneficial results are evidence of unobviousness. *In re Skoll*, 523 F.2d 1392, 187 USPQ 481 (CCPA 1975); *In re Skoner*, 517 F.2d 947, 186 USPQ 80 (CCPA 1975); *In re Gershon*, 372 F.2d 535, 152 USPQ 602 (CCPA 1967).

In order to patent an optical isomer, it is necessary to show that they possess "...qualities [which] are utterly unobtainable" in the racemic mixture. *Sterling Drug v. Watson*, 108 USPQ 37. See also: *Pfizer v. Int. Rectifier Corp.*, 190 USPQ 273, 280; *Lilly v. Generex*, 174 USPQ 65; *In re Volweiler*, 146 USPQ 137 (requiring that the claimed component of an old mixture "be so different in properties and uses as to be in effect a new compound."

Allowable Subject Matter

The elected species remains free of the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached at 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J. Davis/
Primary Examiner, Art Unit 1621
3/7/09